



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JAN - 5 2000

4 8 5 6 '00 JAN 28 P 2 :37

Ms. Katie Ferren
Marketing Director
Optiohealth
500 Citadel Drive
Suite 120
Los Angeles, California 90040-1572

Dear Ms. Ferren:

This is in response to your letter of December 10, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Optiohealth is making the following claim, among others, for the product **Optio Echinacea & Goldenseal Extract**:

“Especially during Cold and Flu season, both herbs help maintain the body’s natural immune arsenal.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease, namely, the common cold and influenza. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA’s Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

LET 324

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Barnett)

f/t:HFS-456:rjm:1/4/00:docname:68635.adv:disc43



500 Citadel Drive Suite 120, Los Angeles, CA 90040-1572 800-796-7846

December 10, 1999

Dr. Elizabeth Yetley
Office of Special Nutritionals
Food and Drug Administration
200 C Street SW
Washington D.C. 20204

Dear Dr. Yetley:

We are offering for sale the following product Optio Echinacea & Goldenseal Extract, with the following Structure/Function claim: Temporarily Assists the Body's Natural Defenses. The supporting side panel story is: This synergistic combination supports the body's immune function in times of stress . Especially during Cold and Flu season, both herbs help maintain the body's natural immune arsenal..

The FDA disclaimer will also appear on the label.

Sincerely,

Katic Ferren
Marketing Director

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